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SILVADENE
(silver sulfadiazine, micronized) CREAM

Actions: Spreads easily and washes off readily with water. Silver sulfadiazine, micronized, has broad antimicrobial activity. Its bactericidal action for many Gram-negative and Gram-positive bacteria as well as being effective against yeast is based on in vitro testing. It acts only on the cell membrane and cell wall to produce its bactericidal effect. Since it is not a carbonic anhydrase inhibitor, SILVADENE Cream may be valuable in treating pediatric burn patients.
Indications: Topical antimicrobial drug indicated as an adjunct for the prevention and treatment of wound sepsis in patients with second and third degree burns.
Contraindications: Since sulfonamide therapy is known to increase the possibility of kernicterus, SILVADENE Cream should not be used at term pregnancy, in premature infants, or on newborn infants during the first month of life.
Warnings: Should be administered with caution to patients with history of hypersensitivity to SILVADENE Cream. If allergic reactions attributable to treatment with SILVADENE Cream occur, discontinue use. *USE IN PREGNANCY:* Not recommended for the treatment of women of childbearing potential unless the burned area covers more than 20 percent of the total body surface area and the need for therapeutic benefits in the physician's judgment is greater than the possible risk to the fetus.
In the treatment of burn wounds over extensive areas of the body, the serum sulfa concentration may approach toxic therapeutic levels (8-12 mg/dl). It would be advisable to monitor serum sulfa concentrations. Renal function should be carefully monitored and the urine should be checked for sulfa crystals.
Precautions: In patients with renal functions become impaired due to accumulation of drug, discontinuation of the drug should be weighed against the therapeutic benefit being achieved. In using topical proteolytic enzymes on an injured area with SILVADENE Cream, the possibility should be noted that silver may inactivate such enzymes.
Adverse Reactions: In an aggregate of 297 patients treated with SILVADENE Cream, there were 59 drug-related reactions (19.9%). Of these, there were 6 cases of burning, 5 of rash, 2 of itching and 1 of interstitial nephritis. However, therapy was discontinued in only 0.9% of the patient population. Across all patients, *no bone marrow* reported. Since significant quantities of silver sulfadiazine are absorbed, it is possible that any of the adverse reactions attributable to sulfonamides may occur.
Dosage and Administration: Apply with sterile, gloved hand to burn area. Apply once to twice daily. Reapply to any areas from which it has been removed by patient activity. Administration may be with or without dressings.
Reduction in bacteria growth after application of topical antibacterial agents has been reported to permit spontaneous healing of deep partial thickness burns by preventing conversion of the partial thickness to full thickness by sepsis. However, reduction in bacterial colonization has caused delayed separation and in some cases necessitating escharotomy in order to prevent contracture.
Treatment should be continued until satisfactory healing has occurred or until the burn site is ready for grafting. *The drug should not be withdrawn from the therapeutic regimen while there remains the possibility of infection except in a significant adverse reaction occurs.*

MARION PHARMACEUTICAL DIVISION
MARION LABORATORIES, INC.
KANSAS CITY, MISSOURI

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My geriatric patient, visibly depressed, said, "It's very hard to grow old alone." "But you have your wife," I reminded him. "She hasn't had a birthday for 15 years," he sighed.

John F. Borelli, M.D.